AUG 17 1999

INTEGRA NEUROCARE LLC

5955 Pacific Center Boulevard • San Diego, CA 92121-4309 • (858) 455-1115 • Fax: (858) 455-8298

K 992006

"NEUROVIEW® INSTRUMENT HOLDER (MODEL 300-33)"

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's name and address:

Integra NeuroCare LLC
5955 Pacific Center Blvd.
San Diego, CA 92121-4309

Contact person and telephone number:

Nancy A. Mathewson
Manager
Regulatory Affairs
(858) 455-1115 X 185

Manufacturing Facility:

Integra NeuroCare LLC
5955 Pacific Center Blvd.
San Diego, CA 92121-4309

Establishment Registration Number: 2023988

Date Summary was prepared: June 11, 1999

Name of the device:

Proprietary Name:	Neuroview® Instrument Holder (Model 300-33)
Common Name:	Endoscope Holder
Classification Name:	Neurological Endoscope (21 CFR 882.1480)

Substantial Equivalence: The Neuroview® Instrument Holder (Model 300-33) is substantially equivalent to the following currently marketed instruments or endoscope holders:

- KSEA Endoscope Holder (K990334)
- Codman Rigid and Steerable Endoscope Holders (K945572)
- Leonard Arm-Support Arm-Endoscope Accessory (K951854)

Device Description: The Neuroview® Instrument Holder, Model 300-33, is a reusable, stainless steel accessory used to hold currently marketed Neuro Navigational Endoscopes. The holder consists of a rail clamp, adjustable stainless steel rods, toggle clamps, and an instrument clamp.

This Instrument Holder, as well as the predicate devices, includes a one-piece design that is completely stable when used to position an instrument. The arms contain adjustable stainless steel clamps and holders that will adapt to any operating room table and hold any Neuro Navigational Endoscope. The holder can be positioned over the patient and locked into place to facilitate accurate Endoscope manipulation and instrument passage. The Instrument Holder, as well as the predicates accessory devices, is sold non-sterile and autoclavable for rapid operating room preparation.

This Instrument Holder is intended to hold the Neuroview Endoscope in place. It has no direct contact with the patient. The only important performance aspect of the Instrument Holder is that it maintains its position once it has been positioned and tightened in place.

Statement of intended use: The Neuroview® Instrument Holder (Model 300-33) is intended for use in holding Neuro Navigational Neuroview Endoscopes in a desired position over the patient during diagnostic and therapeutic procedures.

Comparison of technological characteristics to predicate devices: A feature comparison chart between Neuroview Instrument Holder (Model 300-33) and the currently marketed predicates KSEA Endoscope Holder, Codman® Rigid and Steerable Endoscope Holders and Leonard Arm-Support Arm-Endoscope Accessory is presented in Table 1.

Safety

None of the Neuroview® Instrument Holder (Model 300-33) components have patient, blood, and/or fluid contact. The Instrument Holder is composed of stainless steel materials that are widely used in other instrument and scope holders.

Table 1: Substantial Equivalence Comparison Chart

Parameter	Neuroview® Instrument Holder (300-33)	KSEA Endoscope Holder	Codman® Rigid and Steerable Endoscope Holders	Leonard Arm – Support Arm-Endoscopic Accessory
Manufacturer	Integra NeuroCare LLC	Karl Storz Endoscopey-America, Inc.,	Johnson & Johnson Professionals, Inc	Leonard Medical, Inc
Intended Use	Rigidly Affix Endoscopes	Rigidly Affix Endoscopes	Rigidly Affix Endoscopes	Rigidly Affix Endoscopes
Materials	Stainless Steel	Stainless Steel and Anodized Aluminum	Stainless Steel and Silicone Rubber	Stainless Steel
Means of Mounting	Table Mounted	Table Mounted	Table Mounted	Table Mounted
Adjustable	Yes	Yes	Yes	Yes
Possible to sterilize	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 1999

Ms. Nancy A. Mathewson, Esq.
Manager, Regulatory Affairs
Integra NeuroCare LLC
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K992006
Trade Name: Neuroview® Instrument Holder (Model 300-33)
Regulatory Class: II
Product Code: KOG and GCJ
Dated: June 14, 1999
Received: June 15, 1999

Dear Ms. Mathewson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Russell P. Pagon

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Indications

510(k) Number: K992006

Device Name: Neuroview® Instrument Holder (Model: 300-33)

Indications for Use:

Neuroview® Instrument Holder (Model: 300-33) is intended for use in holding Neuro Navigational Neuroview Endoscopes in a desired position over the patient during diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____
(Per 21 CFR 801.109

Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992006